

REMARKS

Claims 1-19 are pending. Claims 1 and 11 are amended. Claim 6 is cancelled. Claims 9 and 10 have been cancelled previously. Claims 17-19 are withdrawn. The Specification is amended to clarify reference to descriptions set forth therein as filed. No new matter is submitted. Accordingly, entry and consideration of the Amendment filed herewith is respectfully requested.

Applicants submit this Amendment in response to the Final Office Action mailed May 25, 2006 and to request reconsideration of the rejected claims as set forth herein. In the event the Examiner determines that the foregoing amendments do not place this application in condition for allowance, entry of the Amendment is nevertheless respectfully requested in order to place this application in better form for appeal should an appeal be pursued in this matter.

Applicants maintain their assertion of claim 11 as generic to all Species in this application. As explained in the Office Action, the embodiments shown in Figs 1-3 do not show a means for varying the distance of the ultrasonic transducer relative to the tissue, as recited in claim 11. However, the Specification at page 10, paragraph [0030] describes such mechanical means for adjusting the distance between the ultrasonic transducer and the tissue as those shown in Figs. 4A-4G. Thus, the mechanical means of Figs. 4A-4G, identified as separate Species in the Election of Species Requirement mailed September 30, 2005, may be incorporated into the embodiment shown in Figs. 1-3, as indicated in the Specification at paragraph [0030].

Accordingly, claim 11 is generic to the Species represented by Figs. 1-3. Moreover, the Species shown in Figs. 7A & 7B readily incorporate the transducer shown in Figs. 1-3 based upon the description thereof at the Specification at paragraphs [0023], [0024] and [0044], for example. Accordingly, Applicants' maintain the assertion of claim 11 as generic to all Species.

With respect to the Drawings objections raised in the Office Action, the reflector is described in the Specification, page 7, paragraph [0024], for example, as the air gap provided in the window of the applicator, wherein the air gap is an acoustic mirror that reflects energy from the vibratory element also provided in the window. Thus, the air gap is the reflector as recited in the claims. To the extent that a reflector is recited in claim 6, with respect to the elected Species drawn to Figs. 7A and 7B, and based on the Specification as a whole, wherein the reflector and vibratory element are described within an applicator as at paragraph [0024], the artisan would readily understand that the reflector and vibratory element described in paragraph [0044] is intended to be provided in the applicator of Figs. 7A and 7B as otherwise described in the Specification. Such is particularly true where the reflector and vibratory element, and their respective provision in an applicator, are described in detail once, at paragraph [0024], for general application where elsewhere referred to, as at paragraph [0044]. Nevertheless, the Specification is amended to more clearly indicate that the detailed description of the reflector and vibratory element earlier described in the Specification is intended to be applicable subsequently therein as well. Such reflector, in Figs. 7A and 7B, is readily understood by the artisan in view of the Specification (Figs. 2 and 7A-7B, and description thereof), as provided with the compliant member also provided with the applicator shown. Fig. 2 shows an applicator with the reflector and vibratory element mounted therein, and Figs. 7A and 7B show an applicator in which such reflector and vibratory element may be so mounted. Applicants maintain therefore, that all of the features recited in claim 6 are described in the Specification and shown in the drawings as filed and in a manner that is readily understood and appreciated by the artisan. Accordingly, withdrawal of the drawing objection based in the reflector is respectfully requested. Applicants will submit formal drawings in due course after notification of withdrawal of the Drawing objections is received.

In the Office Action, claims 11-16 are rejected under 35 U.S.C. 112, 1st paragraph as allegedly not enabled for failing to show how various energy sources, i.e., ultrasound, microwave, cryoablation, RF, etc., would be used with the electrodes shown in Figures 7A and 7B. Applicants traverse the rejection on this basis however as paragraphs [0043] and [0044] amply describe that the electrodes are “operatively connected to an energy source, for example, ultrasound, microwave, cryoablation, radio-frequency (RF), photodynamic, laser, or cautery.” Moreover, paragraph [0043] further describes that the electrodes through which the energy is provided are “...on the surface of the compliant material...” or “Alternatively or additionally, ... integrated into the surface of the compliant material.” Moreover, a carbon fiber or other conductive material is described for providing the selected energy through electrodes “...woven into a bounding surface of compliant material ...”. Applicants assert that such description more than adequately provides support for the various energies and the configuration of the electrodes relative to the compliant material for providing such energies, as recited in the claims. Accordingly, withdrawal of the 35 U.S.C. 112, 1st paragraph rejection of claims 11-16 on this basis is respectfully requested.

With respect to the 35 U.S.C. 112, 1st paragraph rejection of claims 11-16 based on the alleged failure to describe how an ultrasound transducer is attached to a compliant material or for allegedly failing to show a transducer head with a compliant material, Applicants assert that paragraph [0044] states that “Alternatively or additionally, an ultrasonic vibratory element may be provided in one or both of jaws 1002a, 1002b.”. Thus, when paragraph [0044] is read in view of the description of the earlier described ultrasonic transducer in the Specification, paragraph [0024] with respect to Figure 2, a skilled artisan would readily understand that the applicator of Figs. 7A and 7B recited in claims 11-16 is properly construed as alternatively or additionally comprising such an ultrasonic transducer mounted within the

applicator that becomes the ultrasonic head having the compliant material thereon. Moreover, as discussed above, the compliant material is readily described as incorporating electrodes in or on the surface of the compliant material. Thus, the 35 U.S.C. 112, 1st paragraph issue having been addressed herein, withdrawal of the 35 U.S.C. 112, 1st paragraph rejection of claims 11-16 on the basis of allegedly not describing an ultrasonic transducer in combination with a compliant material is respectfully requested. Thus, contrary to the assertions set forth in the Office Action, Applicants' maintain that the earlier description providing a vibratory element and reflector in Fig. 2 is readily translatable into the applicator of Figs. 7A and 7B based on the description thereof in the Specification at paragraph [0044]. Applicants further maintain that the artisan would readily appreciate the understandings expressed herein based on the Specification and Figures as filed. Accordingly, withdrawal of the 35 U.S.C. 112, 1st paragraph rejection of claims 11-16 is respectfully requested.

In the Office Action, claims 1, 2, 4-6 and 11-14 are rejected under 35 U.S.C. 102(b) as allegedly anticipated by U.S. Patent Publication No. 2002/0042610 to Sliwa, Jr. et al. (hereafter "Sliwa"). The rejection is respectfully traversed.

To maintain a 35 U.S.C. 102(b) rejection, a reference must teach each and every element of a claimed invention. Sliwa does not do so.

Applicants' independent claim 1 recites an applicator for creating a lesion in tissue comprising, *inter alia*, a first rigid or semi-rigid support member, a first compliant material coupled to the first support member, a first passage in communication with the first compliant material for infusing a medium to the compliant material, an air gap reflector provided in at least the first rigid or semi-rigid support member to reflect or focus incident energy, and at least one electrode for conducting energy to an outer surface of the tissue. Applicants' independent claim 11 recites an applicator for creating lesions in tissue comprising, *inter alia*, a first rigid or semi-

rigid support member, an ultrasonic transducer element mounted to the first support member, an air gap reflector provided in at least the first rigid or semi-rigid support member to reflect or focus incident energy, and means for varying the distance between the ultrasonic transducer element and an outer surface of the tissue.

Sliwa is relied on in the Office Action as allegedly disclosing at least the features of Applicants' claims 1 and 11 recited above. Sliwa, however, discloses an ablation device 400 (Figure 67) comprised of a number of adjacent cells 402 each having an ultrasonic transducer element 406 housed within a housing 410 comprised of an enclosure 412 and a top 414. The housing 410 is then mounted into an opening 446 in a suction body 448 that is further provided with suction recesses 454 (Figure 64) for adhering the device 400 to tissue (paragraph [0209]). A distributing element 420 is attached to the transducer 406 (paragraph [0207]), and a compliant membrane 460 is adhered to a bottom of the enclosure 412 (paragraph [0211]). Sliwa fails to teach or suggest the air gap reflector provided in a rigid or semi-rigid support member as recited in each of Applicants' independent claims 1 and 11. Thus, Sliwa fails to teach or disclose the combination of features recited in at least Applicants' independent claims 1 and 11, from which all other claims directly or indirectly depend. Moreover, the cancellation of claim 6 renders any rejection thereof moot. Accordingly, withdrawal of the 35 U.S.C. 102(b) rejection of claims 1, 2, 4-6 and 11-14 based on Sliwa is respectfully requested.

In the Office Action, claims 1-3, 6-8 and 11-16 are rejected under 35 U.S.C. 102(e) as allegedly anticipated by U.S. Patent No. 6,547,788 to Maguire, et al. (hereafter "Maguire"). The rejection is respectfully traversed.

To maintain a 35 U.S.C. 102 rejection, a reference must teach each and every element of a claimed invention. Maguire does not do so.

Applicants' independent claim 1 recites an applicator for creating a lesion in

tissue comprising, *inter alia*, a first rigid or semi-rigid support member, a first compliant material coupled to the first support member, a first passage in communication with the first compliant material for infusing a medium to the compliant material, an air gap reflector provided in at least the first rigid or semi-rigid support member to reflect or focus incident energy, and at least one electrode for conducting energy to an outer surface of the tissue. Applicants' independent claim 11 recites an applicator for creating lesions in tissue comprising, *inter alia*, a first rigid or semi-rigid support member, an ultrasonic transducer element mounted to the first support member, an air gap reflector provided in at least the first rigid or semi-rigid support member to reflect or focus incident energy, and means for varying the distance between the ultrasonic transducer element and an outer surface of the tissue.

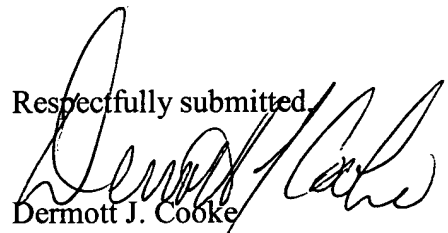
Maguire discloses a tissue ablation catheter assembly 100 comprised of a delivery member 102, an ablation member 128 comprised of an expandable member 108 and an ablation element 120 therein, and an ablation control system 118. An electrical connector 112 connects the ablation control system 118 to the ablation member 128 and ablation element 120. Once the catheter assembly 100 is located in the desired organ, tissue or vessel, then fluid, introduced to the expandable member 108 through tube 113, inflates the expandable member 108, and the ablation element 120 is activated to ablate the targeted tissue and form the desired lesion within the organ, tissue or vessel (col. 22, lines 1-22). The catheter based ablation assembly 100 of Maguire is thus structurally configured to address internal surfaces of an organ, tissue or vessel, which is substantially different than the applicator structurally configured for creating lesions on an outer surface of tissue as recited in Applicants' independent claims 1 and 11, from which all remaining claims directly or indirectly depend. Moreover, with respect to the reflective material 1060 (Fig. 10L as relied on in the Office Action), such reflective material 1060 is actually a filter 1060 (col. 38, lines 52-56) with a pattern thereon to disseminate energy in accord with the

patterned filter. Such patterned filter 1060, even if comprised of a reflective material, differs from the air gap reflector recited in each of Applicants' independent claims 1 and 11, from which all remaining claims ultimately depend. Accordingly, because Maguire fails to teach or disclose the combination of features recited in Applicants' independent claims 1 and 11, withdrawal of the 35 U.S.C. 102(e) rejection of claims 1-3 and 6-16 based on Maguire is respectfully requested. Moreover, the cancellation of claim 6 renders moot any rejection thereof.

Applicants assert therefore, in view of the remarks made herein, that the pending claims are patentable. Accordingly, prompt reconsideration of the application and allowance of all pending claims are respectfully solicited.

Should the Examiner determine that anything further is desirable to place this application in even better form for allowance, the Examiner is invited to contact the undersigned at the telephone number indicated below.

Respectfully submitted,


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